

October 29, 2018

Dr. Scott Gottlieb
Commissioner
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: FDA–2018–N–3240

Re: List of Bulk Drug Substances for Which There is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act

Dear Commissioner Gottlieb:

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On behalf of over 39,000 members of the American College of Emergency Physicians (ACEP), we greatly appreciate the opportunity to provide our comments on the Food and Drug Administration’s (FDA’s) proposed notice related to the list of bulk drug substances that outsourcing facilities may use in compounding under Section 503B of the Federal Food, Drug & Cosmetic Act. The FDA is proposing not to include three bulk drug substances: bumetanide, nicardipine hydrochloride, and vasopressin on the 503B bulk drug substances list.

As the FDA considers whether to finalize this proposal, ACEP asks that the agency take into account how not including any of these substances, especially vasopressin, would affect the ongoing issue that we are facing with drug shortages across the country. Our patients who are experiencing emergencies need access to all medications that are used to treat life-threatening conditions. However, with respect to emergency medicine, the shortage crisis affects drugs across all classes of medications. As of June 2017, there are 69 preparations of 28 emergency care medications that are in shortage, including most forms of adenosine, atropine, bicarbonate, calcium, dextrose, dopamine, epinephrine, fentanyl, furosemide, labetalol, magnesium, lorazepam, and paralytic agents.¹ In May 2018, a major supplier of medications to emergency providers reported there are 156 emergency medication preparations and 50 intravenous fluid preparations that are not available. This will have a significant impact on emergency patient care. Vasopressin is another drug that is currently in short supply, and although it used to be inexpensive and easy to obtain, it is now not used frequently because of its lack of availability.

¹ ACEP Now, “Emergency Departments Need Plan to Deal with Drug Shortages,” Augustine, James J., 2017, August 15, <https://www.acepnow.com/article/emergency-departments-need-plan-deal-drug-shortages/?singlepage=1&theme=print-friendly>

ACEP is extremely pleased that you have convened a new Drug Shortages Task Force that will look for holistic solutions to addressing the underlying causes of drug shortages and we thank you for the ongoing opportunity to actively participate in the Task Force's public listening sessions. Since the Task Force is analyzing all facets of this complicated issue, we hope that it will examine how including or not including certain drugs on the 503B bulk drug substances list would impact the availability of these drugs in emergency departments and other health care settings.

We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs at jdavis@acep.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Vidor E. Friedman". The signature is fluid and cursive, with a large, sweeping flourish at the end.

Vidor E. Friedman, MD, FACEP
ACEP President